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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,483	03/22/2004	Hans-Juergen Kuhr	9134-0252	2791

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EXAMINER

LANG, AMY T

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/806,483

Applicant(s)

KUHR ET AL.

Examiner

Amy T. Lang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

The new grounds of rejection set forth below are necessitated by applicant's amendment filed on 1/15/2007. In particular, claims 1, 2, 4, 6-8, 10, 12, 13, and 16-32. This combination of limitations was not present in the original claims. Thus, the following action is properly made final.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the actuation of the blocking mechanism causing the ring to move to a position so that the needle body is enlarged must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 12** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 discloses a needle body, comprising a protective portion, and connected to a needle. The claim further recites wherein the protective portion and the needle are moved relative to one another. Therefore it is the examiner's position it is unclear how the protective portion can move independently of the needle when the protective portion is "connected" to the needle.

4. **Claims 14 and 24** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 14 and 24 recite wherein the protective portion comprises a magazine housing. However, the claims previously stated that the protective portion and the needle are moved relative to one another. Therefore, it is the examiner's position that it is unclear as to how the magazine housing, in which the lancets are placed, can be moved independently to the lancet needles.

5. **Claims 31 and 32** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31 and 32 both recite wherein the needle moves from a resting position to an activated lancing position multiple times so that the needle is reused. However, claim 21, from which claims 31 and 32 are dependent, discloses wherein a blocking mechanism prevents reuse of the needle. Therefore, it is the examiner's position that these claims are indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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7. **Claims 1-8, 10-12, 13, 14, and 16-25, and 29-32** are rejected under 35 U.S.C. 102(e) as being anticipated by Le Vaughn (US 2005/0015020 A1).

With regard to **claims 1, 5, 8, 9, 10-12, 19, 22, 23, 25, and 30-32**, LeVaughn discloses a lancing aid device (see entire document) comprising a housing and a plurality of lancets ([0009]), which clearly overlaps the instantly claimed multiple use lancing aid. Each lancet comprises a needle tip, which clearly overlaps the instantly claimed lancet system, connected to a body ([0107]). The lancets are arranged on a carrier that is removable ([0014], [0098]). Therefore, each lancet system is removable from the housing.

The lancets tips are secured with a protective cap (147) for sterility ([0107]). The caps are removed prior to puncturing the patient ([0020]). Therefore, the protective caps clearly overlap the instantly claimed protective portion. An opening is provided in the housing for the needle tip to pass through when puncturing the patient ([0108]). A drive mechanism (44) is also provided for to activate the lancet needles ([0106], [0109]).

Once the needle tip (the lancet system) emerges pass the housing to puncture the patient, the lancet system has been removed from the housing (Figures 18, 27A, and 27B).

LeVaughn further teaches the housing comprising a spring element (74), which causes the lancing needle to drive radially outward ([0100]). The spring element interacts with the lancet body connected to the lancet system and clearly overlaps the instantly claimed holding element (Figure 4). After a lancet has been driven to puncture a patient and removed from the housing, control lever (202) advances the lancet carrier

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to then activate the next lancet ([0113] – [0119]). Once the lancet carrier has been advanced, it cannot be retracted. Therefore, the control lever (202) overlaps the instantly claimed blocking mechanism by preventing the spring element (74) to interact and activate a previously fired lancet needle.

With regard to **claim 3**, as shown in Figure 19, the housing comprises several independently acting holding elements wherein a lancet (172) is restrained in each element.

With regard to **claims 14 and 24**, since LeVaughn discloses a magazine carrier comprising a plurality of lancets, it is the examiner's position that the carrier overlaps the instantly claimed protective portion.

With regard to **claim 17**, since the lancet body (8) passes through the holding element of the housing (174 (Figure 4), the shape of each lancet body interacts with the holding element of the housing ([0100]). Therefore, the shape of the lancet body comprises the holding element of the lancet.

With regard to **claim 6**, attention is drawn to Figure 18. LeVaughn discloses an embodiment in which after a first lancet has been fired and removed from the housing and the blocking mechanism activated to advance a second lancet and prevent retraction to the previously fired lancet, the second lancet is now in position to be fired to puncture the patient. This second lancet is initially held within the housing by a holding element, the disclosed disk shaped lancing cartridge ([0109]). Firing of the lancet causes the lancet to be driven radially outward, away from the holding element

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(Figure 18; [0109]). Therefore, actuation of the blocking mechanism causes a second lancet to fire and separate from the holding element.

With regard to **claims 2, 4, and 29**, Figure 18 discloses an embodiment of the lancing aid device of LeVaughn in which a plunger is released from the holding element (disk shaped lancing cartridge), which causes the lancing needle (lancing system) to be driven radially outward from the housing. The last figure in the sequence of Figure 18 discloses the lancing needle retracted after being driven radially outward to puncture the patient ([0109]). As shown in the figure, the needle tip extends beyond the housing. Therefore, LeVaughn discloses a lancing device in which the lancing system is not held within the housing after it is removed.

With regard to **claim 7**, as shown in Figure 18, the lancet needle tip extends beyond the housing when in a resting position. Therefore, the blocking mechanism is actuated when the lancet system is removed from the housing.

With regard to **claims 13 and 21**, LeVaughn also discloses a sterility barrier, a thin film-like cover sealed over each lancet tip, which clearly overlaps the instantly claimed protective portion ([0019], [0106]). Since claim 12, from which claim 13 is dependent, teaches the needle body as comprising the protective portion, it is the examiner's position that the needle body of LeVaughn encompasses the disclosed sterility barrier. When the lancet is fired radially outward, after actuation of the blocking mechanism, the needle tip penetrates through the sterility barrier ([0019], [0106]). Therefore, the shape of the sterility barrier, and therefore the needle body, has changed upon actuation of the blocking mechanism.

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With regard to **claims 16 and 18**, as stated above, it is the examiner's position that the sterility barrier of LeVaughn comprises the needle body. Therefore when the blocking mechanism is actuated and the needle tip penetrates through the sterility barrier, the needle body (sterility barrier) is destroyed and broken. The needle body contacts the holding element of the housing and therefore also overlaps the instantly claimed holding element of the lancing system.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 15 and 26-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Le Vaughn (US 2005/0015020 A1).

With regard to **claim 15**, LeVaughn discloses a lancing aid device in which a lancing body is retained within a housing. Figure 21 discloses wherein the blocking

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mechanism comprises member (220), which contacts the lancet bodies. Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the lancet bodies to comprise component (220) since they move together to activate the next lancet.

With regard to **claims 26-28**, the blocking mechanism (202) as shown in Figure 21, comprises a half circular ring. However, it would have been obvious to one of ordinary skill at the time of the invention for the blocking mechanism to comprise a full circular ring and completely overlap the housing. Puncturing of the sterility barrier causes the barrier to expand and therefore enlarge.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/30/07
Amy T. Lang

ATL



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER